UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to the TPP Trial Subclasses**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

TPP TRIAL DEFENDANTS' TRIAL BRIEF

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STATEMENT OF THE CASE

As the Court is aware, this case arises out of the recall of certain valsartan-containing drugs ("VCDs") that contained trace nitrosamine impurities in the form of either N-Nitrosodimethylamine ("NDMA") or N-Nitrosodiethylamine ("NDEA").

It is undisputed that the VCDs, despite the impurities, were fully effective at treating patients with hypertension or heart failure, among other conditions. As the United States Food and Drug Administration ("FDA") explained, the VCDs' value as blood pressure medication far outweighed any hypothetical risks associated with the impurities at issue. Nevertheless, the recall led to litigation, including the TPP trial claims, which allege that defendants committed common law fraud, violated state consumer protection statutes and breached express warranties by selling medication or API containing impurities that exceeded FDA's later-adopted acceptable daily intake limits.

ANTICIPATED LEGAL ISSUES

A class trial in this action, spanning 42 states and three causes of action, is set to begin shortly. In preparation for that trial, the parties have filed cross-motions for summary judgment, motions to preclude expert testimony under Federal Rule of Evidence 702 and *Daubert*, motions regarding the proper scope of deposition designations, and extensive motions in limine. The vast majority of the parties'

evidentiary and procedural disputes (to the extent they can be predicted prior to trial) are covered by those submissions.[1] In view of the Court's instruction that a trial brief should be used to identify issues likely to arise at trial that have not already been adequately covered by such motions, defendants will not repeat their arguments on those issues. (*See* 2/1/24 Status Conference Tr. 17:13-18:1, ECF 2625.) However, defendants anticipate several issues that have not yet been raised and may arise at (or before) trial: (1) whether plaintiffs can present testimony from an expert witness whose name was disclosed for the first time last week, long after the Court-ordered Rule 26(a)(2) deadline, and who still has not submitted an expert report or disclosure; (2) whether plaintiffs can present testimony from a series of lawyers (also disclosed last week) on issues of pre-suit notice; (3) whether plaintiffs can prove the validity of MSP's assignments through three unauthenticated hearsay documents (one of them also not disclosed until last week); (4) whether plaintiffs may offer Jim McDonald as a "lay" witness to opine on toxicology; (5) whether plaintiffs can selectively (and misleadingly) edit deposition designations instead of including the witnesses' full answers; (6) whether plaintiffs have evidence to "translate" point-of-sale data to point-of-payment data; (7) whether plaintiffs may designate the testimony of retailer and wholesaler co-defendant witnesses to offer unqualified and

[1] Defendants hereby incorporate by reference the arguments and citations to authorities set forth in each of Defendants' pending motions.

prejudicial lay opinions on the meaning of adulteration, the value of the VCDs, and other matters outside of their 30(b)(6) topic designations; and (8) whether plaintiffs can present deposition testimony from witnesses who will appear live at trial.

I. THE COURT SHOULD STRIKE PLAINTIFFS' UNDISCLOSED EXPERT GREG COWHEY.

On March 5, 2024, more than a year after plaintiffs' expert disclosure deadline and less than two weeks before trial was set to begin, plaintiffs disclosed for the first time the name of a new expert, Greg Cowhey. To date, plaintiffs have not provided a written report for Mr. Cowhey as required by Federal Rule of Civil Procedure 26(a)(2), or even disclosed a summary of his opinions. The Court should strike this undisclosed expert from Plaintiffs' witness list and bar him from testifying at trial pursuant to Rule 37(c).

Expert witness testimony must be disclosed "at the times and in the sequence that the court orders." Fed. R. Civ. P. 26(a)(2)(D). Retained experts like Mr. Cowhey are required to provide a written report that includes, among other things, "a complete statement of all opinions the witness will express and the basis and reasons for them" and "the facts or data considered by the witness in forming them." Fed. R. Civ. P. 26(a)(2)(B). "Expert disclosure requirements are meant to ensure the playing field remains level, to afford the opposing party an opportunity to challenge the expert's qualifications and opinions, and to avoid undue prejudice and surprise." *Bouder v. Prudential Fin., Inc.*, No. 06-4359 (DMC), 2010 WL 2026707, at *2

(D.N.J. May 21, 2010).

If a party fails to comply with the disclosure requirements of Rule 26(a), "the party is not allowed to use that information or witness to supply evidence . . . at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). The rule is "self-executing," *id.*, advisory committee's notes to 1993 amendment, and "written in mandatory terms," *Vacarro v. Amazon.com.dedc, LLC*, No. 18-11852 (GC) (TJB), 2024 WL 866776, at *4 (D.N.J. Feb. 29, 2024) (citation omitted). In order to avoid exclusion, the non-disclosing party has the burden of demonstrating either substantial justification or harmlessness. "Substantial justification is defined as 'justification to a degree that could satisfy a reasonable person that parties could differ as to whether the party was required to comply with the disclosure request.'" *Bouder*, 2010 WL 2026707, at *2-3 (quoting *D & D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, No. 03-1026 (MLC), 2006 WL 1644742, at *4 (D.N.J. June 8, 2006)); *see also United States v. Brace*, 334 F.R.D. 472, 478 (W.D. Pa. 2020) ("Substantial justification exists if there is a genuine dispute about whether the party was required to make the disclosure.") (quoting *Kacian v. Brennan*, No. 3:12-cv-102, 2017 WL 933142, at *3 (W.D. Pa. Mar. 8, 2017)). "A failure to disclose is considered harmless 'when there is no prejudice to the party entitled to disclosure.'" *Bouder*, 2010 WL 2026707, at *3 (quoting *D & D Assocs.*, 2006 WL 1644742, at *4). The Third Circuit has identified four factors to

consider in evaluating whether non-disclosure warrants exclusion of evidence: (1) the prejudice or surprise of the party against whom the evidence is offered; (2) the ability to cure the prejudice; (3) likelihood of disruption to trial; and (4) bad faith or willfulness in failing to comply with the district court's order. *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (affirming exclusion of expert testimony that was disclosed more than a year after the expert deadline due to plaintiffs' "flagrant disregard" of the court's pretrial order).

Plaintiffs cannot avail themselves of any exception to the automatic exclusion of Mr. Cowhey because Plaintiffs' belated and deficient disclosure of Mr. Cowhey is neither justified nor harmless.

First, there can be no dispute that plaintiffs were required to disclose Mr. Cowhey, a damages expert, and his written report by the deadline set by the Court: January 20, 2023. (ECF 2190.) Plaintiffs' belated disclosure of Mr. Cowhey's name in a draft pretrial order on March 5, 2024—more than 14 months after the Court's deadline—and their failure to produce any expert report even at that late date is not substantially justified. *See Bouder*, 2010 WL 2026707, at *4 (no substantial justification for disclosing expert report more than three months after disclosure deadline); *Ali v. Lyons*, No. 03-6947, 2005 WL 6042716, at *1 (E.D. Pa. Oct. 4, 2005) (there is "no excuse for the failure . . . to disclose an expert for seven months after the deadline").

Second, plaintiffs' belated and deficient disclosure is not harmless because their untimely disclosure of Mr. Cowhey and failure to produce his expert report would "jeopardize[] defendants' trial preparation." *Ghulam v. Strauss Veal Feeds, Inc.*, No. 1:01-CV-1678, 2002 WL 34381146, at *2 (M.D. Pa. Nov. 5, 2002); *see also M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, No. 97-1568-(JAG), 2007 WL 979854, at *12 n.12 (D.N.J. Mar. 30, 2007) (excluding late-disclosed expert opinion because opposing parties lacked the opportunity to depose expert on his new opinions or "prepare any rebuttal evidence of their own"). Defendants have not had the opportunity to depose Mr. Cowhey, challenge his qualifications and opinions through a Rule 702/*Daubert* motion, "formulate an adequate cross-examination . . . were he to testify at trial," or prepare expert reports in rebuttal. *Ghulam*, 2002 WL 34381146, at *2. "Non-disclosure of expert reports is not harmless because surprise expert testimony leaves the other party susceptible to ambush at trial, contravening the purpose of the discovery rules." *Id.* (striking plaintiff's purported expert witness for failure to disclose a written report by the deadline); *see also Konstantopoulos*, 112 F.3d at 720 (district court's finding of prejudice was justified where expert was disclosed three weeks before trial and no written report was ever produced); *Bouder*, 2010 WL 2026707, at *4 ("tardy disclosure" of expert report during summary judgment briefing was prejudicial).

Finally, exclusion of Mr. Cowhey's testimony is the only appropriate sanction

under the factors identified by the Third Circuit. As discussed above, plaintiffs' belated and deficient disclosure of Mr. Cowhey severely prejudices defendants' ability to prepare for trial, and given that trial is just weeks away, this prejudice cannot be cured without delaying trial and "expending additional time, resources and money." *Bouder*, 2010 WL 2026707, at *4-5 (excluding belated expert report where "there is no reasonable way to cure the prejudice without reopening discovery, delaying resolution of the motion and the case, and forcing [d]efendants to incur additional costs"); *see also Haines v. Davies*, Nos. 1:07-cv-00851 & 1:07-cv-00852, 2009 WL 331433, at *4 (M.D. Pa. Feb. 9, 2009) (precluding expert testimony that was disclosed four weeks before trial because allowing such testimony "would require substantial delay so that [d]efendant could depose [the expert], and potentially prepare its own responsive expert witness"); *Ghulam*, 2002 WL 34381146, at *3 (striking plaintiff's expert witness two months before trial where belated disclosure "would jeopardize the prompt disposition of the case"). Plaintiffs' belated and deficient disclosure is in "flagrant disregard" of the Court's case management order setting their expert discovery deadline for January 20, 2023. *Konstantopoulos*, 112 F.3d at 719-20. Accordingly, all factors weigh in favor of exclusion of Mr. Cowhey's testimony.

For the foregoing reasons, defendants respectfully request that the Court strike Mr. Cowhey as a witness and bar him from testifying at trial.

II. THE COURT SHOULD STRIKE IRRELEVANT LAWYER TESTIMONY ABOUT SUPPOSED NOTICE.

The Court should reject plaintiffs' last-minute attempt to add five previously undisclosed lawyer witnesses, purportedly to testify as to pre-suit notice. The testimony is late-disclosed, and it would be too burdensome at this point to depose five new witnesses. In any event, these individuals are plaintiffs' lawyers, not company witnesses, and therefore would not have personal knowledge of pre-suit notice by the many unnamed class members. To the extent they intend to testify about notice by other individuals, or suggest that notice was fulfilled by filing suit, neither form of testimony would be proper. *See, e.g.*, *Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 590 (S.D.N.Y. Mar. 16, 2021) ("the existence of prior complaints by other consumers cannot satisfy the notice requirement" under New York law); *Brame v. Gen. Motors LLC*, 535 F. Supp. 3d 832, 839 (E.D. Wis. 2021) (pre-suit notice requirement not met because no plaintiffs allege they "***personally*** notified GM" regarding the product issue and that the mere filing of a lawsuit as well as presence of other lawsuits does not fulfill this requirement) (emphasis added); Wyo. CPJI (Civ.) § 13.06 ("A seller is not liable for a breach of warranty unless ***the buyer*** within a reasonable time after he discovers or should have discovered any breach notifies the seller of the [breach].") (emphasis added); *Colpitts*, 527 F. Supp. 3d at 590 ("[E]ven if [d]efendant had been aware of similar suits or customer complaints prior to the filing of this lawsuit, New York's pre-suit notice requirement

still has not been met, as that requirement is intended to 'open[ ] the way for normal settlement through negotiation.'") (citation omitted); *Brame*, 535 F. Supp. 3d at 840-41 ("[t]he purpose of giving notice . . . includes opening a path to settlement talks and giving the seller an opportunity to protect him or herself;" a class action lawsuit "does not inform the seller that each proposed unnamed class member actually considers his or her vehicle defective and in need of warranty service"); *Cole v. C.R. Bard, Inc.*, No. 4:20-CV-01630, 2021 WL 784661, at *5 (S.D. Tex. Feb. 11, 2021) (applying Texas law; "The pre-suit notice requirement is intended to allow the parties to settle their warranty disputes amicably before proceeding with adversarial litigation. It is a condition precedent to filing suit."), *report & recommendation adopted by* 2021 WL 784136 (S.D. Tex. Feb. 26, 2021). In short, it is unclear that these surprise witnesses have any relevant evidence whatsoever, and this sideshow should be prohibited.

Additionally, at least two of the disclosed witnesses, John R. Davis and David Stanoch, have been actively involved as plaintiffs' counsel in connection specifically with this trial, including actively negotiating pretrial issues and taking the depositions of multiple trial witnesses who are expected to appear live or are designated to be presented by video. Given these attorneys' roles as advocates at trial, their testimony is not permitted under Rule 3.7(a) of the Model Rules of Professional Conduct and its state law counterparts, which preclude a lawyer from

acting "as advocate at a trial in which the lawyer is likely to be a necessary witness." Model Rules of Pro. Conduct r. 3.7(a) (Am. Bar Ass'n 2024). Should they testify, defendants will likely have to move for their disqualification.

III. PLAINTIFFS CANNOT PROVE THE VALIDITY OF MSP'S ASSIGNMENTS THROUGH UNAUTHENTICATED DOCUMENTS.

The existence and validity of the assignments on which MSP purports to sue represent a core part of plaintiffs' case.[2] Plaintiffs can try to prove those assignments through documentary evidence, but cannot do so unless they bring the necessary authenticating witnesses to trial.

As the Court is aware, MSP did not make payments for VCDs; rather, it buys assignments in bulk and sues on them. If those assignments are invalid, MSP lacks both standing and any cause of action on the merits. *See, e.g.*, *Riffin v. Consol. Rail Corp.*, 783 F. App'x 246, 248 (3d Cir. 2019) (per curiam); *Shah v. Horizon Blue Cross Blue Shield*, No. 1:16-cv-2528-NLH-AMD, 2018 WL 1509087, at *3 (D.N.J. Mar. 27, 2018). It appears that plaintiffs hope to prove that MSP holds a valid assignment (and therefore a valid claim) based on three documents: one purporting to be the string of assignments from SummaCare with the consideration for the assignments redacted, another purporting to be the string of assignments from EmblemHealth with the consideration for the assignments redacted, and a third

[2] The Court is incorrect that MSP's status as a proper assignee "is not contested." (ECF 2657, at 9.)

(which was produced to defendants for the first time ***less than a week ago***) purporting to be MSP's operating agreement. (*See* ECF 2672-4 (SummaCare assignment); ECF 2672-3 (EmblemHealth assignment); MSP 0005997 (operating agreement) (Davidson Cert. Ex. 1).) The first two purport to assign the claims to certain of MSP's subsidiary series, albeit without disclosing the financial terms as required to assess whether MSP gave adequate consideration for the assignments, while the third purports to give MSP the right to sue on those subsidiaries' behalf. For those documents to be admissible, they require live sponsoring witnesses.

With limited exceptions for self-authenticating documents, *see* Fed. R. Evid. 902, documentary evidence must be authenticated before it can be admitted, *see* Fed. R. Evid. 901; *PDVSA US Litig. Tr. v. Lukoil Pan Ams., LLC*, 991 F.3d 1187, 1190-91 (11th Cir. 2021) (explaining process for authentication in the context of assignment). To do so, the proponent of the document "must produce evidence sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901(a). The most obvious way to do that here would be with a witness with firsthand knowledge of the two contracts and operating agreement and the consideration paid thereunder. *See* Fed. R. Evid. 901(b)(1). But to the best of defendants' knowledge, plaintiffs have not proposed any such witnesses.

Compliance with the authentication rules in this case is much more than an empty formality. Case after case brought by the same group of plaintiffs has been

dismissed for failure to demonstrate (or in some cases even to plead) the validity of the assignments on which the suit has been premised. *See, e.g.*, *MSP Recovery Claims, Series LLC v. Tower Hill Prime Ins. Co.*, No. 1:20-cv-262-AW-HTC, 2022 WL 17839537, at *5 (N.D. Fla. Dec. 20, 2022) ("cannot show that it holds valid assignments"); *MSPA Claims I, LLC v. Infinity Prop. & Cas. Grp.*, 374 F. Supp. 3d 1154, 1164 (N.D. Ala. 2019) ("cannot conclude that [plaintiff] has met its burden of establishing . . . assignment . . . was valid"). In some such cases, the courts have accused plaintiffs of "feign[ing] legitimacy through empty documentation," *MAO-MSO Recovery II, LLC v. State Farm Mut. Auto Ins. Co.*, No. 1:17-cv-01541-JBM-JEH, 2018 WL 2392827, at *1 (C.D. Ill. May 25, 2018), *aff'd in relevant part*, 935 F.3d 573 (7th Cir. 2019), misrepresenting the nature of their assignments, and creating assignments that "never actually existed"—and have even hinted that MSP plaintiffs outright falsify documents, *see MSP Recovery Claims, Series LLC v. N.Y. Cent. Mut. Fire Ins. Co.*, No. 6:19-CV-00211 (MAD/TWD), 2019 WL 4222654, at *4-5 (N.D.N.Y. Sept. 5, 2019) (noting, among other things, that documents purporting to be from different sources all appeared to have been created by the same source).

In any event, regardless of the reputation of the litigant offering them, the rules require documents to be authenticated. The Court should require the rules to be followed here, and plaintiffs have not identified any authenticating witnesses.

IV. THE COURT SHOULD STRIKE JAMES MACDONALD FROM PLAINTIFFS' WITNESS LIST.

As defendants have previously argued in their in limine briefing, the Court should exclude all email correspondence between Dr. James MacDonald and Dr. Charles Wang as hearsay. Plaintiffs have sought to avoid this problem by designating Dr. MacDonald as a live witness. But in so doing, they have traded one problem for another because Dr. MacDonald has not been properly disclosed as an expert and thus cannot testify at trial regarding toxicology or FDA regulations.

James MacDonald is an acquaintance of Charles Wang, who is, in turn, an acquaintance of ZHP employee Min Li. Dr. Wang reached out by email to Dr. MacDonald in July 2018 to discuss the findings of NDMA impurities in valsartan API. In responding to Dr. Wang, Dr. MacDonald stated that NDMA "is a pretty well-known toxin and animal carcinogen" "found in cured meats and some groundwater" and "likely [a] human carcinogen at sufficient exposures." (CHARLESWANG000237 (Davidson Cert. Ex. 2).) He further stated that the test results left ZHP and the product "not [in] a good position" and that the FDA would likely order a recall. (*Id.*) Introducing his testimony at trial about this email would essentially amount to backdoor expert evidence. After all, Dr. MacDonald did not work at ZHP and had no firsthand involvement in the facts of this case. Dr. MacDonald's opinions were not based on any personal experience testing the at-issue VCDs for NDMA or participating in defendant's FDA voluntary recall process.

Moreover, any testimony by Dr. MacDonald would necessarily derive from specialized knowledge that he developed over multiple decades of working on drug safety, toxicology and regulatory approval.[3] *See DVL, Inc. v. Niagara Mohawk Power Corp.*, 490 F. App'x 378, 381 (2d Cir. 2012) (affirming decision to strike opinions as undisclosed expert testimony because witness "relied on technical and scientific knowledge in making most of the observations and conclusions in [his] declarations"). The average lay person would have no knowledge of NDMA, its effect on animals, or where it is commonly found. (*See* CHARLESWANG000237.) Nor would the average lay person have knowledge of the FDA drug recall process or chemistry, manufacturing and controls plans. (*Id.*) Rather, these opinions are precisely the type of expert testimony contemplated by Rule 702 that Dr. MacDonald, who is offered as a lay witness, cannot provide. *See Freedom Wireless, Inc. v. Bos. Commc'ns Grp., Inc.*, 369 F. Supp. 2d 155, 157 (D. Mass. 2005) ("[O]pinions . . . based on [witness's] highly technical and specialized knowledge" are "not the type of lay opinion contemplated by Rule 701, but fall[] within the realm of expert opinion described in Rule 702.").

[3] Dr. MacDonald received his Ph.D. in toxicology in 1975, after which he supervised the development of dozens of new molecular entities before joining a research institute as a senior vice president of drug safety in 1994. *James S. MacDonald, Ph.D.*, Synergy Partners R&D Solutions, https://www.synergymedicines.com/james-s-macdonald-phd.html (last accessed Mar. 13, 2024). Since 2009, Dr. MacDonald has led organizations developing new molecular entities. *Id.*

For these reasons, the Court should preclude Dr. MacDonald from testifying to the contents of his hearsay emails with Dr. Wang.

V. PLAINTIFFS SHOULD BE REQUIRED TO DISCLOSE THEIR MECHANISM FOR "TRANSLATING" STATE DATA.

Defendants recently moved for decertification, pointing out that the subclass definitions for this trial—which are based on the state in which TPPs made payments—do not match either the Court's earlier choice-of-law ruling (based on where those TPPs are headquartered) or the data by which plaintiffs identify class members and calculate damages (based on the state in which a prescription is dispensed). In denying the motion, the Court suggested that there is "a translating mechanism that aligns . . . [p]oint of [s]ale . . . to [p]oint of [p]ayment." (ECF 2657, at 6; *see id.* at 7 ("evidence can be translated"), 8 ("the fix . . . is a translating mechanism").) The court held that the "translating mechanism . . . is up to the parties to realize." (*Id.* at 8; *see id.* at 11 ("once the parties adopt a translating mechanism for locating where the VCDs were paid into where the paying TPPs are located, there will be no misalignment").) However, defendants are aware of no such mechanism, and plaintiffs have never referenced any such mechanism in any briefing, discovery or expert depositions.

Needless to say, any such translating mechanism will have to be presented to the jury at trial, not reserved for post-trial claims administration, since the jury is responsible for apportioning any damages award by state subclasses. Accordingly,

if plaintiffs have a proposal for a "translating mechanism," they need to produce it to defendants (and if they do not have one, they cannot prove their case and there is no need to proceed to trial). It is axiomatic that "our judicial system embraces trial [only] after full and complete discovery." *Columbia Gas Transmission, LLC v. 101 Acres & 41,342 Sq. Ft. More or Less in Heidelberg Twp.*, No. 4:13-cv-00783, 2016 WL 9736117, at *1 (M.D. Pa. Nov. 14, 2016); *see, e.g., Espenshade v. Pa. State Univ.*, 556 F. Supp. 131, 134 (M.D. Pa. 1983) ("the modern discovery rules were promulgated with the purpose of making information accessible" at trial). Yet, with one week until trial was scheduled to begin, plaintiffs still have not given defendants any idea of the mechanism on which their ability to prove this case on a classwide basis depends (assuming such a mechanism exists). They need to do so now.

VI. PLAINTIFFS SHOULD BE PROHIBITED FROM DESIGNATING PARTIAL ANSWERS IN DEPOSITIONS.

It appears that plaintiffs' counsel intend to clip deposition testimony to regularly show the jury only a portion of the witness's answers, and then try to prevent defendants from using the rule of completeness to show the jury the rest of the response.[4] This effort to mislead the jury is fundamentally unfair and should not

[4] For example, Plaintiffs have designated testimony in which Dr. Sushil Jaiswal's answer to a question is interrupted part of the way through by Plaintiffs' counsel, but have not designated the portions of Dr. Jaiswal's answers that follow after those interruptions. (*See, e.g.*, Jaiswal Tr. 334:12-335:3 (Plaintiffs' designation *(cont'd)*

be allowed.

As defendants explained in their opposition to plaintiffs' motion to preclude certain deposition designations (*see* ECF 2661), "[i]f a party introduces all or part of a statement, an adverse party may require the introduction, at that time, of any other part—or any other statement—that in fairness ought to be considered at the same time" notwithstanding any "hearsay objection." Fed. R. Evid. 106; *see* Fed. R. Civ. P. 32(a)(6) ("If a party offers in evidence only part of a deposition, an adverse party may require the offeror to introduce other parts that in fairness should be considered with the part introduced, and any party may itself introduce any other parts.") "The touchstone of Rules 32(a)(4) and 106 is 'fairness.'" *Crowley v. Chait*, No. 85-2441 (HAA), 2004 WL 7338421, at *17 (D.N.J. Dec. 29, 2004); *see, e.g.*, *Bland v. PNC Bank, N.A.*, No. 15cv1042, 2016 WL 10536026, at *4 (W.D. Pa. Dec. 30, 2016) (referring to the rule as "a reaffirmation of the obvious" and "admit[ting] the additional portions" of deposition "pointed to by the opposing party") (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 171 n.14 (1988)).

Plaintiffs have previously suggested that counter-designations can only be used if necessary to provide "absolutely necessary" context. But nothing in the text of either Rule 32 or Rule 106 supports that cramped reading. Instead, defendants

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improperly stops at 334:23); *id.* 446:11-465:14 (Plaintiffs' designation improperly stops at 464:19).)

must be allowed to introduce any portions of depositions necessary to prevent the jury from receiving an incomplete understanding of the full scope of a witness's testimony. In addition to the ordinary fairness concerns that motivate the rule of completeness, the fact that many of the designations involve translations between English and Chinese adds another reason to prohibit plaintiffs' selective editing. Plaintiffs apparently propose to play for the jury the witnesses' entire responses in the original Chinese, but only the most plaintiff-friendly sound bite of the English translation. Jurors will no doubt be confused as to why a long answer in the original language appears so short in translation. For this reason, as well, more complete answers must be played.

VII. PLAINTIFFS SHOULD BE PRECLUDED FROM INTRODUCING TESTIMONY OF THE CORPORATE PHARMACY AND WHOLESALER WITNESSES.

The Court should preclude in its entirety the testimony of eight pharmacy and wholesaler corporate representatives listed by plaintiffs in the pretrial order: Owen McMahon (Rite-Aid), John Holderman (CVS), Cesar Cedeno (Humana), Catherine Stimmel (Walgreens), Daniel Brais (Humana), Steven Taylor (OptumRx), Julie Webb (Cardinal Health), and Wendy Woon-Fat (OptumRx). (*See* Joint Final Pretrial Order ("PTO"), Part V. A. 1.) Plaintiffs have designated these witnesses to "testify regarding [each pharmacy's] inability to sell adulterated drugs as well as Defendants' pre-suit notice/knowledge." (*See id.*) Plaintiffs have further designated

deposition testimony that these fact witnesses are simply not qualified to give, including opinions on the meaning of "adulteration," whether the pharmacies can sell drugs that are adulterated, and whether valsartan pills containing nitrosamines have monetary value. (*See, e.g.*, PTO Ex. 37 ("Cedeno Dep. Designations"); PTO Ex. 35 ("McMahon Dep. Designations"); PTO Ex. 36 ("Holderman Dep. Designations"); PTO Ex. 38 ("Stimmel Dep. Designations"); PTO Ex. 39 ("Brais Dep. Designations"); PTO Ex. 40 ("Taylor Dep. Designations"); PTO Ex. 41 ("Webb Dep.") Designations; PTO Ex. 42 ("Woon-Fat Dep. Designations").) These designations add little, distract from the issues of this trial, and should be precluded in their entirety for four reasons.

First, the probative value of the witnesses' testimony, if any, "is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. The pharmacy and wholesaler corporate witnesses' testimony has little or no relevance or probative value, as it pertains at most to the pharmacies' inability to sell defendants' VCDs following the recall, when post-recall sales are not at issue in this case. *See* Fed. R. Evid. 401, 402. Moreover, plaintiffs have identified multiple other witnesses responsible for addressing the topics of adulteration and monetary value of VCDs—namely,

plaintiffs' experts.[5] Introducing the testimony of pharmacy and wholesaler corporate witnesses who are not parties to this trial and are neither qualified nor disclosed as experts to speak to these same issues would violate every part of Rule 403's balancing test. When the Court measures what relevant, admissible, and non-cumulative information these witnesses add to the case—if any—its value is trivial compared to the risk of "unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403.

The nature of plaintiffs' designated testimony concerns the interpretation of "adulteration," hypotheticals involving the implications of adulterated product, whether pharmacies could sell defendants' VCDs, and whether defendants' VCDs had monetary value. Accordingly, there is a high risk of misleading the jury, confusion of the issues, and unfair prejudice to defendants. Topics related to adulteration and the value of VCDs are technical and call upon specialized knowledge related to the regulation of drug products, drug efficacy, and economics. *See* Fed. R. Evid. 701. The topics are properly the subject of expert testimony and

[5] The pharmacy witnesses' testimony is not only duplicative of plaintiffs' experts' testimony but also duplicative of each other—plaintiffs have designated ***eight*** pharmacy and wholesaler witnesses to cover largely the same ground. (*See* PTO, Part V. A. 1.) At minimum, the testimony of these witnesses should be precluded as cumulative. *See* Fed. R. Evid. 403.

should not be left to the untested opinions of lay witnesses. *See Mack v. Venslosky*, No. 3:10-264, 2023 U.S. Dist. LEXIS 190017, at *10 (W.D. Pa. Oct. 23, 2023) (noting that Rule 403's balancing test places on one side the maximum reasonable probative force for the offered testimony versus the likely prejudicial impact of the evidence). The pharmacy witnesses' testimony also interposes undue delay, wastes time, and needlessly presents cumulative evidence, wasting the very limited time the parties have to try this case with unhelpful testimony on subjects addressed by other witnesses.[6] These reasons alone are enough to preclude the witnesses' testimony. *See* Fed. R. Evid. 403; *see also* Fed. R. Evid. 401, 402.

Second, the testimony is improper opinion testimony of lay witnesses, as it concerns the pharmacy defendants' interpretation of "adulteration" and the implications thereof. *See* Fed. R. Evid. 701. This Court has held that legal opinions about how the FDA applies the term "adulteration" are not helpful to the

[6] This waste of time would be compounded by the fact that the jury would not only be hearing plaintiffs' designated testimony but also any counter-testimony defendants may need the jury to consider. *See* Fed. R. Evid. 106. Plaintiffs' designations in many instances include only portions of a question or a partial answer, and/or a question or answer alone, rather than the full question and full answer from the deposition. Even the questions and answers that are not excerpted lack important context—such as the fact that these topics are outside the witnesses' designated scope and their personal knowledge. Accordingly, if plaintiffs are permitted to play this testimony for the jury, the amount of additional testimony that would need to be added to ensure fairness would necessarily be significantly more than plaintiffs have designated.

factfinder. (*See* ECF 2581, at 6, 8, 17, 19.) The Court has held that the term "adulterated" is "legally nuanced," and that a number of the parties' proffered experts are not qualified to opine on the interpretation of that term. (*See, e.g.*, ECF 2261, at 93.) These pharmacy witnesses, who have not been designated as expert witnesses by any party and hold no specialized knowledge on these issues, are even less qualified to opine on the issue. *See* Fed. R. Evid. 104(a).

Third, the witnesses' testimony is beyond the scope of the Rule 30(b)(6) topics designated for these witnesses and is not within their personal knowledge as required by Rule 602. *See* Fed. R. Evid. 602. Plaintiffs have designated testimony indicating the witnesses are testifying in a representative capacity on behalf of their respective companies for certain topics, but they have conspicuously omitted any explanation of the scope of those topics, as well as the fact that the designated testimony that follows is outside the topics' scope. Failing to explain the scope of the designated topics makes the danger of unfair prejudice and jury confusion all but guaranteed if plaintiffs are then permitted to introduce substantive testimony that falls ***entirely outside*** of the witnesses' designated topics, but gives the misleading impression that the witnesses are testifying within their corporate capacity to matters within the scope of their representative testimony. For all eight witnesses, for example, plaintiffs designate testimony about the witnesses' interpretation of the term "adulteration," hypotheticals about what their employers would or would not

do with adulterated product, or what is or is not permitted to be done with adulterated product; but such testimony is not within the scope of the Rule 30(b)(6) topics for ***any*** of these witnesses. Thus, plaintiffs' designations will mislead the jury into believing that these witnesses are able to competently testify on behalf of their employers on issues that are outside of their personal knowledge and on which they were not prepared to testify for their employers. The same is true for the other designations for these witnesses, which include, for example: what a nitrosamine is, what a hypothetical patient would or would not buy, reasons for recalling the drugs, and whether a pill is "worthless" if it contains nitrosamines (Cedeno Dep. Designations); hypotheticals about what Walgreens "wants to do" in dispensing product, personal interpretation of recall documents (as opposed to what the documents themselves say) (Stimmel Dep. Designations); whether nitrosamines were disclosed (McMahon Dep. Designations); and what Rite Aid or CVS would do in a hypothetical involving contaminated product (McMahon and Holderman Dep. Designations).

Each of these topics was outside of the respective witness's Rule 30(b)(6) topics, and each witness lacks personal knowledge to speak to these topics as fact witnesses. (*See* ECF 1509, 1512, 1525, 1527.) Further, many of the designated questions are hypotheticals or call for speculation as to what another person or entity would do or want, and thus would only be appropriately asked of designated experts.

For this reason as well, these witnesses' designations should be precluded in their entirety.

Fourth, plaintiffs have not shown the witnesses to be unavailable and therefore cannot use their deposition testimony consistent with the rule against hearsay. Plaintiffs seek to play the deposition testimony of the pharmacy and wholesaler defendants without calling them live. (*See* PTO, Part V. A. 1.) But deposition testimony is admissible under the hearsay rule only ***if the declarant is unavailable to testify***. *See* Fed. R. Evid. 804(b)(1); Fed. R. Evid. 802. Moreover, the proponent of the hearsay deposition testimony bears the burden of showing the declarant's unavailability. *See, e.g.*, *United States v. Parcel of Real Prop. Known as 6109 Grubb Rd.*, 886 F.2d 618, 622 (3d Cir. 1989) (noting that proponent of using deposition testimony bears burden of showing unavailability and that unavailability cannot be premised solely on the fact that the proponent does not feel the declarant's presence at trial is necessary). Here, plaintiffs have stated no basis for unavailability, including, but not limited to, whether the witnesses in question are located more than 100 miles from the Court. *See, e.g.*, Fed. R. Civ. P. 32(a). Accordingly, to the extent the Court is not inclined to preclude the testimony for the above reasons, plaintiffs should nonetheless be precluded from introducing the testimony of the pharmacy defendants via playing their depositions at trial, as opposed to calling them live, as

they have not made a showing that the witnesses are unavailable.[7]

VIII. PLAINTIFFS MAY NOT TAKE UNTIMELY FINANCIAL CONDITION DISCOVERY.

On February 23, 2024, just 23 days before the originally scheduled trial date and years after the close of fact discovery, Plaintiffs served Defendants for the first time with a document titled "Plaintiffs' Notice to TPP Bellwether Trial Defendants to Produce Evidence of Financial Condition At Trial" ("Notice to Produce"), seeking seven categories of documents purportedly relating to Defendants' financial condition: financial statements, tax returns, bank statements, asset documentation, income documentation, liabilities, and trusts and other entities. The Notice to Produce purports to demand a response prior to March 18, 2024, and purports to demand objections within five (5) business days. The Notice to Produce does not identify the rule under which it is issued or the basis for Plaintiffs' untimely discovery demands for previously unrequested financial condition documents. Plaintiffs should be precluded from taking such discovery for multiple reasons.

[7] In the event the Court is inclined to allow testimony from the pharmacy and wholesaler witnesses, whether live or by video, the jury should have to hear from these witnesses only once, and defendants should be entitled to conduct a complete examination at that time, or to play defendants' affirmative designations chronologically at that time, without limitation as to scope or completeness. Otherwise, there remains the potential that the witnesses would have to twice take the stand (or be played on video), further compounding the difficulties of trying this case efficiently in the allotted four-week time period. *See* Fed. R. Evid. 611(a).

First, Plaintiffs' Notice to Produce is neither timely nor the proper procedural vehicle by which to request this evidence. *See Galloway v. Islands Mech. Contractor, Inc.*, No. 2008-071, 2013 U.S. Dist. LEXIS 5232, at *19 (D.V.I. Jan. 14, 2013) (quashing subpoenas "filed after the close of discovery" as "untimely"). As this Court recently reaffirmed, fact discovery in this case closed nearly three years ago in June of 2021, making these requests "clearly untimely." (ECF 2469 at 7-8.)

Second, Plaintiffs' Notice to Produce violates Fed. R. Civ. P. 16(b) in deviating from the Court's scheduling orders and modifying the schedule without good cause or the Court's consent. *See* Fed. R. Civ. P. 16(b)(4) ("A schedule may be modified only for good cause and with the judge's consent."). Plaintiffs have not shown good cause for this untimely request as they had ample time to request such evidence during discovery. *See Zimmerman* v. *Edwin A. Abrahamsen & Assocs*., No. 15-CV-1174, 2017 U.S. Dist. LEXIS 137629, at *11 (M.D. Pa. Aug. 28, 2017) ("'With respect to diligence, to establish good cause, the party seeking an extension should show that more diligent pursuit was impossible.' Thus, if a more diligent approach was possible, and the delayed request was 'simply the result of carelessness or error,' that request to reopen the discovery period must be denied.") (citation omitted).

Third, to the extent MSP intended to serve a trial subpoena, that does not change the fact that these are untimely requests. "Trial subpoenas may be used to secure documents for trial preparation or to ensure the availability at trial of original documents previously disclosed by discovery." *E.E.O.C. v. Smokin' Joe's Tobacco Shop, Inc.*, No. 06-1758, 2007 WL 3287429, at *2 (E.D. Pa. Nov. 7, 2007) (citing *Puritan Inv. Corp. v. ASLL Corp.*, No. Civ.A. 97-1580, 1997 WL 793569 (E.D. Pa. Dec. 9, 1997)). "However, trial subpoenas may not be used as a means of engaging in discovery after the discovery deadline has passed." *Smokin' Joe's*, 2007 WL 3287429, at *2 (citing *BASF Corp. v. Old World Trading Co.*, No. 86 C 5602, 1992 WL 24076, at *2 (N.D. Ill. Feb. 4, 1992); *Hatchett v. United States*, No. 94-CV-74708-DT, 1997 WL 397730, at *3 (E.D. Mich. Feb. 28, 1997)).

Fourth, Plaintiffs' instructions to "produce the requested documents and information at trial on March 18, 2024, or within three business days prior to trial" do not comply with Fed. R. Civ. P. 34. Even if Plaintiffs' Notice had been properly issued, Rule 34 requires a minimum of 30 days for a party to respond absent a party stipulating to or a court ordering a shorter time to respond. *See* Fed. R. Civ. P. 34(a)(2)(A) ("The party to whom the request is directed must respond in writing within 30 days after being served or – if the request was delivered under Rule 26(d)(2) – within 30 days after the parties' first Rule 26(f) conference.").

Fifth, insofar as the requested discovery appears to be directed to Plaintiffs' punitive damages case, Defendants have moved for summary judgment on the issue of punitive damages because Plaintiffs have failed to present any evidence that Defendants acted with the requisite culpability to support a punitive damages award. (*See* ECF 2562-1 at 37-43.)

Sixth, Teva and Torrent have individually and separately moved for summary judgment on the issue of punitive damages because Plaintiffs have specifically failed to present any evidence that Teva or Torrent even knew of the NDMA or NDEA impurity or intended to sell products that contained such impurities until ZHP informed them of the existence of the impurities, precluding any demonstration of willful, malicious, or egregious misconduct, or the exacting state-of-mind or culpability standards required to recovery punitive damages on any of Plaintiffs' claims in any state. (*See* ECF 2565-1 at 8-9; ECF 2570-1 at 7-8.) Because the available evidence "cannot support a finding of 'evil-minded motives'" or "conduct that exhibited a 'wanton' disregard for the plaintiffs' rights" by Teva or Torrent, Plaintiffs' prayer for punitive damages cannot proceed against them. *Walter v. Holiday Inns, Inc.*, 784 F. Supp. 1159, 1181 (D.N.J. 1992). And without a viable punitive damages claim, Plaintiffs are not entitled to discovery solely related to punitive damages.

Seventh, Plaintiffs' second through seventh requests (for tax returns, bank

statements, asset documentation, income documentation, liabilities, and trusts and other entities) are overly broad, unduly burdensome, untimely, not relevant to any claim or defense, and not proportional to the needs of the case, insofar as these documents provide no information regarding Defendants' financial condition that would not be encompassed within Defendants' financial statements. Plaintiffs have also failed to establish a compelling need for confidential communications between Defendants and government authorities or financial institutions like tax returns and bank statements, whose disclosure is limited as a matter of public policy. These requests also seek information that is not relevant with respect to punitive damages in light of Plaintiffs' failure to timely disclose an expert who could use these materials to provide testimony regarding Defendants' financial condition.

IX. PLAINTIFFS SHOULD NOT BE ALLOWED TO USE DEPOSITION DESIGNATIONS IN LIEU OF QUESTIONING WITNESSES THAT ARE PRESENT LIVE.

Jucai Ge (a current ZHP employee), Hai Wang (a former Solco employee), Dr. Sushil Jaiswal (a current Torrent employee), and Dawn Chitty (a former Torrent employee) are all scheduled to testify live at trial. Mr. Wang (who lives in New Jersey) has been subpoenaed by plaintiffs, while Ms. Ge, Dr. Jaiswal, and Ms. Chitty will be offered as witnesses in defendants' case-in-chief. Plaintiffs are aware that these witnesses will appear at trial (in Mr. Wang's case at their demand), but have nevertheless designated portions of their deposition that they wish to play, as

substantive evidence, in addition to live testimony. The Court should prohibit this duplicative evidence.

Although the Rules permit "[a]n adverse party [to] use for any purpose the deposition of . . . the [opposing] party's officer, director, managing agent, or designee,"[8] Fed. R. Civ. P. 32(a)(3), that right remains subject to the general principle that a court "should exercise reasonable control over the mode and order of examining witnesses . . . so as to . . . make those procedures effective for determining the truth," Fed. R. Evid. 611(a). It also remains subject to the long-established "preference for live testimony" where available. *ADT-Am. Co. v. Krueger Int'l, Inc.*, No. 12-00032, 2014 WL 3952848, at *19 (E.D. Pa. Aug. 12, 2014) (citation omitted). As such, "courts have precluded the playing of deposition testimony and required live testimony—even of officers, directors, and managing agents—when the adverse witness is available to testify live." *Micron Tech., Inc. v. Rambus Inc.*, No. 00-792 (SLR), 2007 WL 9771144, at *2 (D. Del. Aug. 29, 2007). That is all the more true where the witness is not just available to testify live but actually present and testifying. *See, e.g., ADT-Am.*, 2014 WL 3952848, at *19-20

[8] Defendants assume, for the sake of argument, that these witnesses constituted officers or managing agents of one of the defendants at the time of their depositions such that they come within the literal scope of Rule 32.

(rejecting argument that plaintiff could play deposition testimony from witness already on the stand; such presentation was "redundant").

That is so for two reasons. The first is the general principle that "testimony by deposition is less desirable than oral testimony and should ordinarily be used as a substitute only if the witness is not available to testify in person." *ADT Am.*, 2014 WL 3952848, at *19 (citation omitted). Plaintiffs themselves have repeatedly extolled this preference for live testimony, arguing that defendants should be precluded from presenting deposition testimony even from witnesses who are ***unavailable***. (*See* ECF 2647-1, at 3 (plaintiffs contending that "the 'truth seeking purpose of litigation' is inhibited by deposition rather than live testimony'").) The second is that presenting deposition testimony from live witnesses would needlessly bifurcate their testimony. Ordinarily, a live witness is subject to direct examination, followed by cross-examination, in an efficient package that jurors can easily comprehend. Here, by contrast, plaintiffs propose to divide the testimony in two, offering deposition clips, followed by live testimony from the same witnesses. This "haphazard and rambling presentation of redundant" evidence would pointlessly confuse the jury and prolong proceedings.[9] *ATD-Am.*, 2014 WL 3952848, at *20.

[9] In addition, given plaintiffs' extremely narrow view of the rule of completeness, discussed above, their proposal could allow them to present cherry-picked snippets of Ms. Ge's, Mr. Wang's, Dr. Jaiswal's, and Ms. Chitty's deposition *(cont'd)*

Dated: March 14, 2024

Respectfully submitted,

By: */s/ Jessica Davidson*
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testimony while requiring defendants to wait weeks to call them and provide context in their case-in-chief.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 14, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
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